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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/770,773	01/26/2001	George Verlaan	05032-00009	7775

7590

07/29/2003

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EXAMINER

KWON, BRIAN YONG S

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 07/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/770,773

Applicant(s)

VERLAAN ET AL.

Examiner

Brian S Kwon

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 April 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-45 is/are pending in the application.
- 4a) Of the above claim(s) 40 and 43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12, 17-25, 27-39, 41, 42, 44 and 45 is/are rejected.
- 7) ☒ Claim(s) 13-16, 26 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Applicants Response To Restriction Requirement Acknowledged

1. Applicants election with traverse the Group I, claims 33-39 and 44-45, is acknowledged. Applicants traverse the restriction requirement on the grounds that there would be no burden in searching the entire groups. This argument is not persuasive, as claimed invention would be distinctive, each from the other for the reason of the record. Furthermore, the search of the entire groups in the non-patent literature (a significant part of a through examination) would be burdensome. Therefore. The requirement is still deemed proper, and made Final. Claims 40 and 43 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected claims, the requirement having been traversed in Paper No. 11.

The product claims (claims 1-32 and 41-42) are examined along with the elected invention. Currently, claims 1-39, 41-42 and 44-45 are pending for prosecution on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 44 and 45 provide for the use of one or more of the compounds of the group consisting of a methylamine and/or flavonolignan, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim Rejections - 35 USC § 101

3. Claims 44 and 45 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 8-9 and 35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 8 further limits the claim 1 by reciting “one or more carbohydrates comprise glucose and at least one of the monosaccharides chosen from the group of fructose, galactose, mannose, ribose and inositol”. In view of claim 8 limitation, the least number of carbohydrates that are presented in said composition are two; glucose and another selected from the group consisting of fructose, galactose, mannose, ribose and inositol. However, the claimed composition may contain only one carbohydrate according to wording of “one or more carbohydrates”. Such inconsistency leads to unclarity of the claimed subject matter.

Claim 35 recites “a physiologically or symptomatically related disorder”. It is not clear what type of diseases or conditions are referred to as “a physiologically or symptomatically

Art Unit: 1614

related disorder". The instant application fails to define the terminology. Applicants are requested to clarify.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-2, 5-8, 11, 23-24, 29, 32-35, 37, 39, 41-42 and 44-45 are rejected under 35 U.S.C. 102(b) as being anticipated by Simone (US 5397786).

Simone teaches a hypotonic rehydration drink, comprises 1 to 30mg of betaine and methionine, choline, 1 to 100g of carbohydrates (e.g., glucose, maltodextrins, fructose, ribose, mannose, etc...), 2 to 2500mg of minerals (e.g., magnesium, calcium, sodium, potassium, etc...), vitamins (e.g., vitamin C, vitamin E, etc...), wherein said composition is useful for treating dehydration symptoms due to exposure to high temperature and/or heavy physical exercise, severe diarrhea or vomiting for a variety of causes such as gastrointestinal disorders, cardiovascular disorders, and chronic illnesses such as cancer (column 2, line 45 thru column 4, line 22; Table 1; column 5, lines 37-55; Claims 13-14 and 17-18).

Although the reference is silent about "an osmolarity of 300 mOsm/l or less" (claim 2), such characteristic or property must be deemed inherent to the claimed hypotonic rehydration drink.

6. Claims 1, 5-8, 11-12, 17-24, 29, 32 and 41-42 are rejected under 35 U.S.C. 102(b) as being anticipated by Hageman (WO99/03365).

Art Unit: 1614

Hageman (WO99/03365) discloses a hypotonic enteral nutritional supplement, comprises a methyl amine (e.g., betaine, choline), methionine, carbohydrates (e.g., maltodextrin and sucrose), minerals (e.g., magnesium, calcium, sodium, potassium, etc...), taurine and vitamins (e.g., vitamin A, vitamin D, tocopherol, vitamin K, vitamin B6, etc...), which is intended for the treatment or prophylaxis of cardiovascular diseases, inflammatory diseases, autoimmune diseases, cancer, wound healing after surgery, decubitus, allergic conditions and etc.... (abstract; Examples, claims 1-10). As one of specific embodiment of the inventions, Example 4 specifically discloses an enteral supplement comprising 0.2g/l of betaine; 165g/l of carbohydrates (100.5g/l of maltodextrin+60g/l of sucrose) 0.04g/l of taurine; 350mg/l of magnesium; 60mg/l of zinc; 2.3g/l of calcium; and 20mg/l of iron.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

Art Unit: 1614

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 3-4, 9-10, 12, 17, 19, 21, 30-31, 36 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Simone (US 5397786).

The teaching of Simone has been discussed in above 35 USC 102(b) rejection.

The referenced teaching differs from the claimed invention in the specific dry mass content of ingredients in said composition (claim 3); the specific amounts of active and inactive ingredients in a composition (claims 4, 9-10, 12, 17, 19, 21, 31); the specific mixtures of carbohydrates in a composition (claims 9-10); the specific pH of the claimed composition (claim 30); the administration of the claimed composition before, during or after the subject is undergoing surgery (claim 36); and the administration of said composition to elderly person (claim 38).

However, all the ingredients employed herein are known to be useful in preparing hypotonic rehydration drink. It would have been apparent to those skilled in the art to optimize amounts of known active and inactive ingredients in a composition; the specific pH of the final composition; the dry mass of the ingredients in a composition; the specific mixtures of kwon

Art Unit: 1614

digestible carbohydrates (e.g., glucose, fructose, galactose, mannose, ribose, inositol); and concurrent administration regimens as determined by good medical practice and the clinical condition of the individual patient.

8. Claims 20 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Simone (US 5397786) in view of Kampinga et al. (US 6455511 B1).

The teaching of Simone has been discussed in above 35 USC 102(b) rejection.

Kampinga teaches or suggests a rehydration composition containing trehalose, saccharides (e.g., glucose, fructose, mannose, galactose, sucrose, maltose, lactose, maltodextrins and glucose polymers), mineals (e.g., calcium, magnesium, zinc, iron, etc...), vitamins and amino acids, wherein said composition is prepared in either isotonic or hypotonic solution (column 4, lines 51-64; claims).

The referenced teaching differs from the claimed invention in the use of zinc and iron in said composition. To incorporate such teaching into the teaching of Simone, would have been obvious in view of Kampinga who teaches or suggests the use of zinc and iron in rehydration solution.

Above references in combination makes clear that the use of minerals such as zinc and iron in hypotonic solution is old and well known. Above references in combination makes clear that the formulation containing betaine, methionine, one or more digestible carbohydrates (e.g., glucose, fructose, galactose, mannose, ribose and inositol), minerals and vitamins are old and well known.

9. Claims 25 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Simone (US 5397786) in view of Kuznicki et al. (US 5464619).

Art Unit: 1614

The teaching of Simone has been discussed in above 35 USC 102(b) rejection.

Kuznicki teaches or suggests a rehydration composition containing flavanols, electrolytes, carbohydrates or carbohydrate derivatives (e.g., fructose, glucose, maltodextrin, glycerol), caffeine and vitamins (abstract, column 4, lines 53-61; column 6, lines 37-44).

The referenced teaching differs from the claimed invention in the use of glycerol and caffeine in said composition. To incorporate such teaching into the teaching of Simone, would have been obvious in view of Kuznicki who teaches or suggests the use of glycerol and caffeine in rehydration solution.

Above references in combination makes clear that the use of caffeine and glycerol in rehydration solution is old and well known. Above references in combination makes clear that the formulation containing betaine, methionine, one or more digestible carbohydrates (e.g., glucose, fructose, galactose, mannose, ribose and inositol), minerals, caffeine, glycerol and vitamins are old and well known.

10. Although the instant claims use the different names for the said ingredients than those taught in the cited references, these references are particularly pertinent and relevant because all the claimed species and their roles are well taught in the cited reference. Thus, one would have been motivated to combine these references and make the modification because they are drawn to same technical fields (constituted with same ingredients and share common utilities, and pertinent to the problem which applicant concerns about. MPEP 2141.01(a). Applicant has presented no evidence to establish the unexpected or unobvious nature of the claimed invention,

Art Unit: 1614

and as such, the claims (3-4, 9-10, 12, 17, 19, 20-22, 25, 28, 30-31, 36 and 38) are properly rejected under 35 U.S.C. 103.

Allowable Subject Matter

11. Claims 13-16, 26 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

12. No Claim is allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Kwon whose telephone number is (703) 308-5377. The examiner can normally be reached Tuesday through Friday from 9:00 am to 7:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725. The fax number for this Group is (703) 308-4556.

Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

Application/Control Number: 09/770,773

Page 10

Art Unit: 1614

Brian Kwon

ZOHREH FAY
PRIMARY EXAMINER
GROUP 1600

A handwritten signature in black ink, appearing to read 'Zohreh Fay', with a stylized flourish at the end.